



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/815,926

04/02/2004

Chien-Hsuan Han

21077-8

9426

28221

7590

11/03/2008

PATENT DOCKET ADMINISTRATOR

LOWENSTEIN SANDLER PC

65 LIVINGSTON AVENUE

ROSELAND, NJ 07068

EXAMINER

WINTERBERG, NISSA M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

11/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/815,926

Applicant(s)

HAN ET AL.

Examiner

Nissa M. Westerberg

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 - 24, 57 is/are pending in the application.
- 4a) Of the above claim(s) 18, 19 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 - 17, 20, 21, 23, 24, 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 29, 2008 has been entered.

Response to Arguments

Applicants' arguments, filed July 29, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 – 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 13 – 24 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims of the instant application recite a variety of limitations regarding what percentage of the drug must be released after certain periods of time in either simulated gastric fluid or simulated intestinal fluid and the location of the release in the intestinal tract. In the figures, the release profiles of various formulations are provided but the composition of these formulations is not given. In the text, a variety of formulations are prepared but no information regarding the release profile of these formulations is provided. In example 11, baclofen is administered to patients and their plasma levels of baclofen are measured. While such information can indirectly provide information regarding the release profile of the dosage form, no indication as to the formulation of the composition administered is given. Therefore, the specification provides insufficient written description for the composition(s) of the pharmaceutical dosage forms that provide the release profiles as claimed in the instant application. Applicant has not provided a description as to how a dosage form that meets the functional limitations of the claim are formulated.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 13 – 16, 20, 21, 23, 24 and 57 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (US 4,780,463) in view of Vishwanathan et al. (US 2002/0119192). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 29, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that controlled release polymers disclosed by Vishwanathan et al. included in the Markush group of claim 13 are only in addition to the necessary and mandatory component of a carboxyvinyl polymer, an item not included in the Markush group. The present claims exclude carboxyvinyl polymer by virtue of the “consisting essentially” of terminology. As the carboxyvinyl polymer is required by Vishwanathan et al., this reference teaches away from a baclofen formulation which necessarily does not include a carboxyvinyl polymer.

These arguments are not found to be persuasive. Applicants have not defined which element(s) materially affect the basic and novel characteristics of the controlled release component. The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) “A consisting essentially of claim occupies a middle ground between closed claims that are written in a consisting of format and fully open claims that are drafted in a comprising format.” PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ

893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In *re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) **MPEP 2111.03**

Additionally, the preamble of the claim uses the completely open language of "comprising" and in the absence of evidence regarding what materials are excluded from the controlled release component, these claims are interpreted using the open language of comprising and the claims are rendered obvious by the combination of *Sunshine et al.* and *Vishwanathan et al.*

8. Claims 13 – 17, 20 21, 23, 24 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Sunshine et al.* and *Vishwanathan et al.* as applied to claims 13 – 16, 20 21, 23, 24 and 57 above, and further in view of *Fara* (US 2003/0031711). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 29, 2008 and those set forth below.

Applicant traverses this rejection on the basis that Fara does not cure the deficiencies of Sunshine et al. and Vishwanathan discussed above.

As discussed above, the combination of Sunshine et al. and Vishwanathan et al. is not deficient in regards to the controlled release polymer, and therefore Fara need not remedy that deficiency.

9. Claims 13 – 16, 20, 21, 23, 24 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. and Vishwanathan et al. as applied to claims 13 – 16, 20, 21, 23, 24 and 57 above, and further in view of Patel et al. (US 6,248,363). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 29, 2008 and those set forth below.

Applicant traverses this rejection on the basis that Patel et al. does not cure the deficiencies of Sunshine et al. and Vishwanathan discussed above.

As discussed above, the combination of Sunshine et al. and Vishwanathan et al. is not deficient in regards to the controlled release polymer, and therefore Patel need not remedy that deficiency.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M – F, 8:00 a.m. – 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW